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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,076	03/02/2006	Toshiyuki Takagi	DAISAN126512	3081

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EXAMINER	
BETTON, TIMOTHY E	

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
07/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efiling@cojk.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/555,076	**Applicant(s)** TAKAGI ET AL.	
	Examiner TIMOTHY E. BETTON	**Art Unit** 1627	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 May 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627

Continuation of 13. Other: In consideration of applicants' disclosure that full consideration was not rendered in view of applicants alleged claim of unexpected results (see page 7 in the first paragraph) , applicants attention is directed to the current specification of record filed on 28 October 2005. Examples begin on page 24 and conclude on page 31. Within these designated pages, this Examiner is specifically asking for clarity in where it specifically and adequately explains unexpected results drawn to anything distinct set aside from what the normal administration of these active agents would affect. The fact that a property or pathophysiological change had occurred initially unobserved cannot be considered unexpected results as these said changes albeit unrecognized were not initally known, observed or made the focus of experimental consideration. Further, the references as applied are found adequate in as far as Kondo, Ellsworth, Weyer, and Orsi consider the end-user, the human subject. The Examples as disclosed in pages 24-31 are merely animal studies which while being a suitable indirect indicator as to how drugs effect the human beings, is not deemed to be the focus of endeavor in this invention. In the alternate, if unexpected results are drawn to the effects in laboratory mice, applicants should clearly indicate so. Applicants further assert on page 7 in the 3rd paragraph that the test subjects of Kondo et al. teach incongruities in view of determining adiponectin levels based upon administration with HMG-CoA reductase inhibitors. In consideration of this Examiner's comments reiterated by applicants at the bottom of page 6 in view of the paragraph bridging pages 7 and 8 of the same set of remarks, the reference is still proper for what it shows in as far as the well-established and art-known agents of the claimed invention are currently marketed and administered for an array of disorders which treat hyperlipidemia inter alia metabolic disorders. As for Ellsworth et al., the relevance lies in the administration of HMG-CoA reductase inhibitors and the effects associated with such administration. Weyer et al. is proper for showing the keen relationship between inter alia obesity and hyperlipidemia in as far as antihyperlipidemics are currently administered adjunctively in therapy regimens for patients with inter alia obesity issues. Finally, Orsi et al. teach a fundamental aspect in the way safer administration of the active agents of applicants invention.